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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/423,534	12/14/99	LAU	M 1-14746

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/423,534	Applicant(s) LAU, MATTHIAS	
	Examiner Thanh X Luu	Art Unit 2878	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 23-43 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 23-43 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. This Office Action is in response to the preliminary amendment filed December 14, 1999. Claims 23-43 are currently pending.

Claim Objections

2. Claims 23-27, 30, 31, 35, 36, 38, 39 and 42 are objected to because of the following informalities:

In claim 23, lines 2, 5, 14, Applicant uses the terms "at least one layer" and "the layer" to refer to the same element. Examiner recommends using consistent terminology. In line 8, "the fluorescent light" lacks proper antecedent basis. In lines 23-24, "the measurable fluorescence intensity" lacks proper antecedent basis.

In claim 24, "the part of the measuring head which holds the outer end" lacks proper antecedent basis.

In claim 25, "the upper measuring head region" lacks proper antecedent basis.

In claim 26, "the filter" lacks proper antecedent basis.

In claim 27, "the measuring head end" and "the fluorescing layer" lack proper antecedent basis.

In claim 30, "the upper measuring head region" lacks proper antecedent basis.

In claim 31, "the exciting light" lacks proper antecedent basis.

In claim 35, "the end face" lacks proper antecedent basis.

In claim 36, "the two limbs" lacks proper antecedent basis.

In claim 38, Applicant should claim the invention, not what "can be" done with the invention since anything "can be" introduced into the support as claimed.

In claim 39, as understood, "the body" lacks proper antecedent basis since the claim states transparent body or a scattering surface.

In claim 42, "the upper heated region" and "the lower region" lack proper antecedent basis.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 23-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 23, line 3, it is unclear what "contains a fluorescing material" modifies, the layer or the support. In line 6, it is unclear from its given context what the phrase "which is directed through" refers to. In line 13-15, it is unclear what "taking account of their numerical apertures and/or with reference to at least one layer containing a fluorescing material" means in its given context. In line 15, it is unclear what is "being applied to the support." In line 19, it is unclear what is used "for exciting light." Further in line 19, "for fluorescent light" does not make sense. In lines 20-21, it is unclear how three optical conductors can be arranged opposite one another in pairs. In

line 22, it is unclear what "a local assignment of the measurable fluorescence intensity" means in its given context. Lastly, Applicant uses the terms optical conductors to refer to different optical conductors throughout the claim. It is unclear how many optical conductors are claimed or which optical conductors are referred to in the claim.

Regarding claim 26, it is unclear which optical conductor Applicant is referring to.

Regarding claim 27, it is unclear if "a plurality of optical conductors" refers to a different set of plurality of optical conductors or the same ones as claimed in claim 23. Furthermore, it is unclear how the plurality of optical conductors is functionally related to the first and second optical conductors or to the rest of the elements of the invention.

Regarding claims 28 and 29, it is unclear what "exciting light" and "reference light" refers to. Furthermore it is unclear how many optical conductors or to which optical conductors are referred to. It is also unclear how conductors or which conductors are arranged in an alternating fashion. That is, the conductors are alternating with what?

Regarding claim 35, it is unclear what "its" refers to. Further it is unclear if "a layer" and "a fluorescing material" refers to another layer or material, or the same layer and material as claimed in claim 23.

Regarding claim 36, it is unclear which optical conductor the claim is referring to.

Regarding claim 39, it is unclear if "an optical conductor" and "a layer" refers to additional conductors or layers or to the conductor and layer already claimed in claim 23. It is also unclear how a surface "points" to a layer.

Regarding claim 41, it is unclear where reflected light comes from.

Regarding claim 42, it is unclear which region the light source and detector are held in.

Claims 24, 25, 30-34, 37, 38 and 40 are indefinite by virtue of their dependency on an indefinite claim.

5. Claim 43 provides for the use of a device for measuring fluorescence, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 43 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 23-29, 31-37, 39-41 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pederson et al. (U.S. Patent 5,319,975).

Regarding claims 23, 26, 29, 39 and 43, as understood, Pederson et al. disclose (see Figures 1 and 6) a device detecting fluorescence-quenching (see column 3, lines 42-44) and for measuring fluorescence excited by light, which has at least one layer (8) applied to a support (6) or a transparent body, the layer contains a fluorescing material, the device having at least one light source (61) which emits light of at least one wavelength that excites the fluorescence in the layer, the light is directed through the support onto the layer by at least one first optical conductor (10), the fluorescence being directed by at least one second optical conductor (12) onto at least one detector (69) for determining the intensity of the fluorescence, the optical conductors are inclined at different angles (at 2), characterized in that the end faces of the first and second optical conductors are arranged relative to one another and applied to the support, the first and second optical conductors are arranged opposite one another in a pair. Pederson et al. further disclose (see Figure 6) a filter (63) arranged between the light source and the first optical conductor. Pederson et al. also disclose a housing (4) for holding the optical conductors. Pederson et al. do not specifically disclose the light source, the detector and the optical conductors held in a measuring head. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to dispose the elements of Pederson et al. in a measuring head to provide a compact and portable device. Further, since the Pederson et al. already teaches of the functional elements of the present invention, it would require only routine skill in the art to dispose those elements within a single housing.

Regarding claims 24 and 25, Pederson et al. do not specifically disclose the

structure of the measuring head. However, the specific structure of a measuring head or housing is a matter of design choice. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to make the measuring head or housing of the device of Pederson et al. flexible or partially bent in order to more easily maneuver the device upon use or to make the device fit more easily into certain spaces.

Regarding claim 27, Pederson et al. discloses (see Figure 1) two optical conductors arranged pointing towards the layer. Pederson et al. do not disclose enough conductors to make up a ring shape. However, the number and arrangement of optical conductors is a matter of design choice. It is well known in the art to bundle smaller optical conductors to make up a larger optical conductor as desired. Furthermore, a ring shape arrangement is the most optimal arrangement for bundling optical conductors. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to provide further optical conductors arranged in the shape of a ring in the device of Pederson et al. to reduce costs or provide more light as desired.

Regarding claim 28, Pederson et al. further do not disclose an outer ring and an inner right. However, an arrangement in which optical conductors carrying light to a target is arranged in an outer ring and optical conductors carrying light from the target to a detector is arranged in an inner ring is notoriously well known. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to provide such an arrangement in the apparatus of Pederson et al. in order to provide

more uniform illumination and improve detection.

Regarding claims 31, 33 and 34, Pederson et al. disclose (see Figure 1) the support is transparent and mounted in an exchangeable fashion in a housing. Pederson et al. further disclose the support is constructed in an elongated fashion in a plane. Pederson et al. do not specifically disclose the type of support. However, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to provide at least a partially polished support region in the apparatus of Pederson et al. in order to obtain better detection. Furthermore, the division of the support into different regions is a matter of design choice.

Regarding claim 32, Pederson et al. do not disclose the reflections as claimed. However, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to provide total reflection as claimed in the apparatus of Pederson et al. in order to obtain maximum fluorescence and improve detection.

Regarding claims 35-37, Pederson et al. do not disclose the support having an angular surface or a u-shape as claimed. However, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to provide the support of Pederson et al. with an angular surface or a u-shape to diverge or separate the exciting light and the fluorescent light and improve detection. The particular arrangement of the u-shape is a matter of design choice.

Regarding claim 40, Pederson et al. do not disclose the transparent body (6) being wavelength-selective. However, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to make the body (6) of

Pederson et al. wavelength-selective in order to reduce unwanted radiation and improve detection.

Regarding claim 41, Pederson et al. only disclose one detector. Pederson et al. do not disclose a further detector as claimed. However, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to provide a further detector in the apparatus of Pederson et al. to monitor the light source for failure.

8. Claims 30, 38 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pederson et al. as applied to claim 23 above, and further in view of Wagner (U.S. Patent 5,001,054) and Bessman et al. (U.S. Patent 4,431,004).

Regarding claims 30 and 38, Pederson et al. do not disclose a heater or a temperature sensor as claimed. Wagner discloses (see Figure 2) using a device having conductors and a fluorescing layer for monitoring glucose. Bessman et al. further disclose (see column 2, lines 37-45) that glucose sensors are temperature dependent and (see Figure 4) disposing a temperature sensor proximate a glucose sensor. Thus, Wagner recognizes that the device of Pederson et al. can be modified to detect glucose and Bessman et al. recognize the sensitivity of glucose sensors to temperature. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to provide a heater and a temperature sensor in the apparatus of Pederson et al. in view of Wagner and Bessman et al. to obtain better detection. The heater and temperature sensor can be introduced into the support of Pederson et al. in view of Wagner and Bessman et al. as desired.

Regarding claim 42, Pederson et al. do not disclose insulating the light source

and detector. However, as stated above, Bessman et al. discloses that monitoring glucose is dependent on temperature. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to insulate the light source and detector in the apparatus of Pederson et al. in view of Wagner and Bessman et al. to reduce the affect of the heat from the light source and detector from affecting the detection, and thereby improve detection.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thanh X. Luu whose telephone number is (703) 305-0539. The examiner can normally be reached on Monday-Friday from 6:30 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Seungsook Ham, can be reached on (703) 308-4090. The fax phone number for the organization where the application or proceeding is assigned is (703) 308-7722.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0956.

txl
August 24, 2001

Que T. Le
Primary Examiner